

REMARKS

The Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the reasons that follow.

I. Status of the Specification and the Claims

While not agreeing with the Office's characterization of the measurement of an angle of repose on p. 4 of the Office Action, the paragraph starting from line 20 to line 26 on p.7 of the Specification as filed is amended to clarify the reference to the measurement of an angle of repose. The description thereof can also be found in the Test Examples in the present Specification. Further discussion can also be found in the next section.

Claim 34 is combined with independent claim 5, which is further amended to clarify the presently recited compound and the ratio. Support thereof can be found in, *inter alia*, the Abstract, third paragraph of the DISCLOSURE OF THE INVENTION section, and the Test Examples in the present Specification. Claim 34 is thus cancelled. Claims 22-24 are amended to correct for minor informalities. The Applicants reserve the right to pursue the subject matter of the any of the cancelled claims in a continuation application. No new matter is introduced, and claims 5-6 and 22-33 are pending to be examined on their merits.

The Applicants further respectfully submit that the objections to claims 22-24 are rendered moot by the foregoing amendments.

II. Claim Rejections – 35 U.S.C. § 112

Claims 5-6 and 22-34 are rejected under 35 U.S.C. § 112, ¶ 2, as allegedly being indefinite. While not necessarily agreeing with the Office, the Applicants have amended the present claims and respectfully submit that the rejections are obviated by the foregoing amendments. Specifically:

Claims 5 and 6

The weight ratio of the surfactant to the compound in present claim 5 is rephrased to provide clarification. The Applicants respectfully submit that as the result of the amendment, the use of “about” is clear and refers to the **range** recited. This description is particularly clear in view of the doctrine of *ejusdem generis*. Specifically, wherever the recited range is disclosed in the present Specification, the “about” in the disclosed ranges before and after the recited range refers to the **range** being described, not a specific number. For example, the third paragraph of the DISCLOSURE OF THE INVENTION section describes the weight ratio as “...about 0.01 to about 2 [“about” describes the range of 0.01 to 2]...about 0.005 to 0.05 [“about” describes the range of 0.005 to 0.05]. Thus, everything in between these two, including the presently recited range of “0.001 to less than 0.1,” should be construed in parallel to the same. The claim language in claim 6 further supports such reading.

Claims 22-24

As described in the previous section, the Applicants respectfully submit that the Office’s characterization of the measurement of the term “angle of repose” is incorrect. At the outset, the Applicants respectfully submit that an “angle of repose” is a term of art that can be readily appreciated by one of ordinary skill in the art to describe an engineer property of a granular material. A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

Contrary to the Office’s assertions, the angle has little to do with the stream of granules flowing from the funnel; rather, the angle relates to the angle between the **surface** of the powder dropped onto a horizontal surface and the **horizontal surface**. This is particularly evident in the descriptions provided in the Test Examples in the present Specification.

Additionally, the Office's assertion that the measurement of an angle of repose requires 20 g of the granulated product is incorrect; and, as noted also by the Office, such 20 g of the product is merely illustrative. For example, the angle of repose as described in Test Example 1 is measured for 300 mg, and not 20 g, of a granulated component. Because an angle of repose describes a material property, the measurement thereof is independent of the amount of the material being measured – i.e., a powder in any amount above a certain level would show the same angle of repose.

Claim 25

The Applicants respectfully submit that the Office's interpretation of the term "additive" in claim 25 is unreasonable. The Office's attempt to construe "additive" as referencing the recited "compound" or "surfactant," when the Specification has specifically described each of these terms, is improper. An "additive" is readily appreciated by one of ordinary skill in the art to refer to an additional constituent that is not the main component. Furthermore, the present Specification specifically describes "additives" as excipient, lubricant, binder, disintegrant, thickener, coating agent, preservative, antioxidant, colorant, sweetening agent, etc. *See* from line 25 on p. 14 to line 4 on p. 17 of the present Specification for a host of additives that is different from the recited compound or the surfactant.

Therefore, at least in view of the foregoing, the Applicants respectfully request that the rejections be withdrawn.

III. Claim Rejections – 35 U.S.C. § 102

Claims 5-6 and 22-33 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 02056881, or its equivalent US 2004/0115264 ("Blouquin"). Claims 5-6, 22-26, and 34 are rejected under 35 U.S.C. §§ 102(a), 102(e) as allegedly being anticipated by US 6,660,296 ("Debregeas"). The Applicants respectfully traverse these rejections.

Blouquin

While not acquiescing to the grounds of the rejections, the Applicants incorporate the recitation of claim 34, which is not rejected under 35 U.S.C. § 102 over Blouquin's teachings, into independent claim 5. As a result of the amendment, because Blouquin does not teach each and every element recited in present independent claim 5, Blouquin's teachings cannot anticipate claim 5 or its corresponding depending claims.

Debregeas

Debregeas' teachings also do not anticipate present independent claim 5. The Office's assertion on p. 7 of the Office Action that Debregeas teaches the presently claimed particle size is incorrect. At the outset, the microgranule disclosed in Debregeas contains a neutral granular support, which is coated with an active layer containing diltiazem, a surfactant, and a binder (e.g., Debregeas, col. 1, lines 54-59). By the Office's analogy, the presently claimed granulated product would be comparable to a coating of on a granular support. This comparison is improper.

Further, the average diameter of 0.4-0.9 mm in col. 3, line 1 of Debregeas refers to the natural granular support, which has little to do with the presently claimed granulated product comprising the presently claimed surfactant and compound. In fact, nowhere does Debregeas disclose the size of a granulated product, as recited in present claim 5. Because Debregeas does not teach each and every element recited in present independent claim 5, Debregeas' teachings cannot anticipate claim 5 or its corresponding depending claims.

Inherency

In addition to the foregoing, the Applicants further respectfully submit that the Office's assertion with respect to inherency over the teachings of both Blouquin and Debregeas is improper. An angle of repose is a property of the material. At the outset, as explained above, both Blouquin and Debregeas do not disclose the granulated products as recited in the present

claims, much less a "structurally identical" product made by substantially identical process." Office Action, p. 7. The Office has not established any evidence for the latter. In fact, as described above, the Office has misanalogized Debregeas' teachings with the presently claimed granulated products. As a result, the presently claimed angles of repose in claims 22-24 are **not necessarily present** in the teachings of Blouquin and Debregeas. In accordance with MPEP § 2112, the Office's alleged inherency is improper.

IV. Claim Rejection – 35 U.S.C. § 103

Claims 5-6 and 22-34 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Debregeas. The Applicants respectfully traverse the rejection.

(i) Current Obviousness Standard

The U.S. Supreme Court reaffirmed the Graham factors for determining obviousness in *KSR Int'l Co. v. Teleflex Inc.* (No. 04-1350) (U.S., April 30, 2007). The Graham factors, as outlined by the Supreme Court in *Graham et al. v. John Deere Co. of Kansas City et al.*, 383 U.S. 1 (1966), are: 1) determining the scope and contents of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; 3) resolving the level of ordinary skill in the pertinent art; and 4) evaluating evidence of secondary consideration. The Supreme Court recognized that a showing of "teaching, suggestion, or motivation" to combine the prior art to meet the claimed subject matter could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a) and held that the proper inquiry for determining obviousness is whether the improvement is more than the predictable use of prior art elements according to their established functions. The Court noted that it is "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed and specifically stated:

Often, it will be necessary . . . **to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in**

the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit.

KSR Int'l Co. v. Teleflex Inc., slip op. at 14 (emphasis added). As discussed below, the cited art cannot render the claimed invention obvious.

(ii) *The present claims are non-obvious over the teachings of Debregeas*

As explained above, the Office has misconstrued Debregeas' teachings to analogize them with the presently claimed granulated products. Specifically, Debregeas does not at all teach or suggest the presently claimed granulated products by a granulation process with the specific, presently recited particle size, as reflected in the amount of the product passing through a 100-mesh sieve. In fact, the two-layer coated tablet of Debregeas is very different from the presently claimed granulated products and could not have provided the unexpected improvement in the granulatability of a compound with poor wettability as in the presently claimed granulated products. Thus, contrary to the Office's assertion on p. 9 of the Office Action, it would not have been obvious for one of ordinary skill in the art to reach the presently claimed granulated products based on Debregeas' teachings. Even assuming, *arguendo*, that one were to employ Debregeas' teachings, the unexpected success in improving granulatability of a compound with poor wettability as provided in the presently claimed granulated products rebuts any *prima facie* case of obviousness.

Therefore, at least in view of the foregoing, the Applicants respectfully request that the rejections be withdrawn.

CONCLUSION

The Applicants believe that the present application is now in condition for allowance and respectfully request favorable reconsideration of the application.

The Office is invited to contact the undersigned by telephone if a telephone interview would advance the prosecution of the present application.

The Office is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, the Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date

Feb. 12, 2010

By



FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Stephen B. Maebius
Attorney for the Applicants
Registration No. 35,264